Attorney's Docket No.: 13751-045003 / A008 DIV2



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

blicant: Michele Sanicola-Nadel et al.

Art Unit: 1642

Serial No.: 10/668,936

Examiner:

Filed

: September 23, 2003

Title

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: RET LIGAND (RETL) FOR STIMULATING NEURAL AND RENAL

**GROWTH** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Under 35 U.S.C. §120, this application relies on the earlier filing date of application serial number 09/187,906, filed on November 6, 1998. Those references listed on the enclosed form PTO-1449 that were submitted to and/or cited by the Office in the prior application are not provided in this application.

This statement is being filed before the receipt of a first Office Action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 13751-045003.

Respectfully submitted,

Date: Norante 15, 2004

Jack Brennan

Reg. No. 47,443

Fish & Richardson P.C.

45 Rockefeller Plaza, Suite 2800 New York, New York 10111

Telephone: (212) 765-5070 Facsimile: (212) 258-2291

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Substitute Form PTO-1449

U.S. Department of Commerce Patent and Trademark Office Attorney's Docket No. Application No. 13751-045003 10/668,936

Information Disclosure Statement
by Applicant
se several sheets if necessary)

Applicant
Michele Sanicola-Nadel et al.

Filing Date

Group Art Unit

September 23, 2003

1642

SADE	U.S. Patent Documents						
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,514,544	05/07/1996	Rao et al.			
	AB	5,607,918	03/04/1997	Eriksson et al.			
	AC	5,693,495	12/02/1997	Breiteneder et al.		:	
	AD	5,770,696	06/23/1998	Warren et al.		-	
	AE	6,025,157	02/15/2000	Klein et al.			
	AF	6,455,277	09/24/2002	Fox et al.			

	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner	Desig.	Document	Publication	Country or			-	lation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AG	0 846 764	06/10/1998	Europe				
	AH	1 010 432	06/21/2000	Europe				
	AI	WO 95/16709	06/22/1995	WIPO				
	AJ	WO 96/14861	05/23/1996	WIPO				
	AK	WO 97/11964	04/03/1997	WIPO				
	AL	WO 97/11965	04/03/1997	WIPO				
	AM	WO 97/18240	05/22/1997	WIPO				
	AN	WO 97/19693	06/05/1997	WIPO				
	AO	WO 97/19694	06/05/1997	WIPO				
	AP	WO 97/19695	06/05/1997	WIPO				
	AQ	WO 97/30722	08/28/1997	WIPO				
	AR	WO 97/33912	09/18/1997	WIPO				
	AS	WO 97/34567	09/25/1997	WIPO				
	AT	WO 97/40152	10/30/1997	WIPO				
	AU	WO 98/32458	07/30/1998	WIPO				
	AV	WO 98/36072	08/20/1998	WIPO				
	AW	WO 98/45708	10/15/1998	WIPO				
	AX	WO 98/46737	10/22/1998	WIPO				

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Drawline through citation if no	t in conformance and not considered. Include conv of this form with

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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 13751-045003	Application No. 10/668,936	
Information Dis	closure Statement	Applicant Michele Sanicola-Nade	el et al.	
(37 CFR §1.98(b))	heets if necessary)	Filing Date September 23, 2003	Group Art Unit 1642	
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Y	Foreign Patent Documents or Published Foreign Patent Applications								
E	Examiner	Desig.	Document	Publication	Country or			Trans	slation
	Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
		AY	WO 98/54213	12/03/1998	WIPO				

	Other D	ocuments (include Author, Title, Date, and Place of Publication)
Examiner	Desig.	
Initial	ID	Document
	AZ	Ausebel et al., 1991, Purification of Proteins by Precipitation. Current Protocols in Molecular Biology, pp. 10.61.1-10.16.11
	AAA	Baloh et al., 1997, Neuron 18:793-802, "TrnR2, a Novel Receptor That Mediates Neurturin and GDNF Signaling through RET".
	ABB	Beck et al., 1995, Nature 373:339-341, Mesencephalic Dopaminergic Neurons Protected by GDNF from Axotomy-Induced Degeneration in the Adult Brain
	ACC	Buj-Bello et al.,1997, Nature 387:721-724, Neurturin Responsiveness Requires a GPI-Linked Receptor and the Ret Receptor Tyrosine Kinase
	ADD	Cao, T., 1995, "c-ret and signal transduction," Cancer Bulletin, 47/2:119-124
	AEE	Creedon et al., 1997, Proc. Nat. Acad. Sci. USA 94, Neurturin Shares Receptors and Signal Transduction Pathways with Glial Cell Line-Derived neurotropic Factor in Sympathetic Neurons.
	AFF	Durbec et al., 1996, Development 122:349-358, Common Origin and Developmental Dependence on C-Ret of Subsets of Enteric and Sympathetic Neuroblasts
	AGG	Durbec et al., 1996, Nature 381:789-793, GDNF Signalling Through the Ret Receptor Tyrosine Kinase
	АНН	Edery et al., 1994, Nature 367:378-380, Mutations of the RET Proto-Oncogene in Hirschsprung's Disease
	AII	Eng et al., 1996, Seminars in Medicine of the Beth Israel Hospital, Boston: 335:943-951, The RET Proto-Oncogene in Multiple Endocrine Neoplasia Type 2 and Hirschsprung's Disease
	AJJ	Gash et al., 1996, Nature 380:252-255, Functional Recovery in Parkinsonian Monkeys Treated with GDNF
	AKK	Gattei et al., 1997, Blood 89:2925-2937, Expression of the RET Receptor Tyrosine Kinase and GDNFR-alpha in Normal and Leukemic Human Hematopoietic Cells and Stromal Cells of the Bone Marrow Microenvironment
	ALL	Henderson et al., 1994, Science 266:1062-1064, GDNF: A Potent Survival Factor for Motoneurons Present in Peripheral Nerve and Muscle.
	AMM	Hillier, L. et al., 1995 The WashU-Merck EST Projecty170a10.s1 Homo Sapiens cDNA Clone 43207 3', EMBL Database Entry HS619153, Accession No. H05619.
	ANN	Hillier, et al., 1996, The WashU-Merck EST Projectmj11d08.r1 Sores mouse embryo MbME13.5 14.5 Mus musculus cDNA clone 475791 5', EMBL Database Entry MMAA49894, Accession No. AA049894, Dec. 31, 1996.
	AOO	Hillier, L., et al., The WashU-Merck EST Projecty170a10.rl Soares infant brain 1NIB Homo Sapiens cDNA clone Image: 43207 5', mRNA sequence, GenBank Accession No. H12981
	APP	Hillier, L., et al., The WashU-Merck EST Projectye83h05.r1 Soares fetal liver spleen 1NFLS Homo sapiens cDNA clone Image: 124377 5', mRNA sequence, GenBank Accession No. R02249
	AQQ	Hillier, L., et al., 1996, Generation and Analysis of 280,000 Human Expressed Sequence Tags, Genome Research, 6:807-828

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Substitute Form PTO-1449 (Modified)	•		Application No. 10/668,936	
***************************************	losure Statement plicant	Applicant Michele Sanicola-Nadel et al.		
(Use several sheets if necessary) (37 CFR §1.98(b))		Filing Date September 23, 2003	Group Art Unit 1642	

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Examiner	Desig.	Danimant
Initial	ID ARR	Document  Hillier, L. et al., 1995, The WashU-Merck EST Projectye83h05.s1 Homo Sapiens cDNA Clone 124377 3', EMBL Database Entry HS13571, Accession No. R02135.
,	ASS	Hofstra et al., 1994, Nature 367:375-376, A Mutation in the RET Proto-oncogene Associated with Multiple Endocrine Neoplasia Type 2B and Sporadic Medullary Thyroid Carcinoma
	ATT	Jing et al., 1996, Cell 85:1113-1124, GDNF-Induced Activation of the Ret Protein Tyrosine Kinase is Mediated by GDNFR-alpha, a Novel Receptor for GDNF
	AUU	Klein et al., 1997, Nature 387:717-721, A GPI-Linked Protein that Interacts with Ret to Form a Candidate Neurturin Receptor
	AVV	Kotzbauer et al., 1996, Nature 384:467-470, Neurturin, a Relative of Glial-Cell-Line-Derived Neurotrophic Factor
	AWW	Lederman et al., 1991, A Single Amino Acid Substitution In a Common African Allele of the CD4 Molecule Ablates Binding of the Monoclonal Antibody, OKT4," Mol. Immun. 28(11):1171-1181
	AXX	Li et al., 1980, Beta-Endorphin omission analogs: Dissociation of immunoreactivity from other biological activities," PNAS USA 77(6):3211-3214
	AYY	Lin et al., 1993, Science 260:1130-1132, GDNF: A Glial Cell Line Derived Neurotrophic Factor for Midbrain Dopaminergic Neurons
	AZZ	Lin et al., 1975, Structure-Function Relationships in Glucagon: Properties of Highly Purified Des- His-, Monoiodo-, [Des-Asn(28), Thr(29)] (homoserine lactone 27)- glucagon. Biochemistry 14(8): 1559-1563
	AAAA	Lindsay, Ronald M., 1995, Nature 373:289-290, Neuron Saving Schemes
	ABBB	Lindsay, Ronald M. and George D. Yancopoulos, 1996, Neuron 17:571-574, GDNF in a Bind with Known Orphan Accessory Implicated in New Twist.
	ACCC	Lo, Liching and David J. Anderson, 1995, Neuron 15:527-539, Postmigratory Neural Crest Cells Expressing c-RET Display Restricted Developmental and Proliferative Capacities
	ADDD	Marra, M., et al., The WashU-HHMI Mouse EST Project mj08d05.r1 Soares mouse embryo NbME13.5 14.5 Mus musculus cDNA clone IMAGE: 475497 5', mRNA sequence, GenBank Accession No. AA050083
	AEEE	Mason, I., 1996, The GDNF receptor: Recent progress and unanswered question," Mol. Cell. Neurosci., 8(2-3):112-119.
	AFFF	Massague, Joan, 1996, Nature 382:29-30, Crossing Receptor Boundaries.
	AGGG	Moore et al., 1996, Nature 382:76-79, Renal and Neuronal Abnormalities in Mice Lacking GDNF
	АННН	Oppenheim et al., 1995, Nature 373:344-346, Developing Motor Neurons Rescued from Programmed and Axotomy-Induced Cell Death by GDNF
	AIII	Pachnis et al., 1993, Development 119:1005-1017, Expression of the C-Ret Proto-Oncogene During Mouse Embryogenesis
	AJJJ	Pandey, A. et al., 1995, The Ret receptor protein tyrosine kinase associates with the SH2-containing adapter protein Grb10, Journal of Biological Chemistry, 270:21461-21463.
	AKKK	Pasini, B., et al., 1996, RET mutations in human disease," Trends In Genetics, 12(4):138-144
	ALLL	Pichel et al., 1996 Nature 382:73-76, Defects in Enteric Innervation and Kidney Development in Mice Lacking GDNF

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	Other Do	ocuments (include Author, Title, Date, and Place of Publication)
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	AMMM	Robertson, Katherine and Ivor Mason, 1997, TIG:13:1-3, The GDNF-RET Signalling Partnership
	ANNN	Romeo et al., 1994, Nature 367:377-378, Point Mutations Affecting the Tyrosine Kinase Domain of the RET Proto-oncogene in Hirschsprung's Disease
	A000	Sanchez et al., 1996, Nature 382:70-73, Renal Agenesis and the Absence of Enteric Neurons in Mice Lacking GDNF
	APPP	Santoro et al., 1995, Science 267:381-383, Activation of RET as a Dominant Transforming Gene by Germline Mutations of MEN2A and MEN2B
	AQQQ	Schuchardt et al., 1994, Nature 367:380-383, Defects in the Kidney and Enteric Nervous System of Mice Lacking the Tyrosine Kinase Receptor Ret
	ARRR	Suvanto et al., 1997, Human Molecular Genetics 6:1267-1273, Cloning, mRNA Distribution and Chromosomal Localisation of the Gene for Glial Cell Line-Derived Neurotrophic Factor Receptor beta, a Homologue to GDNFR-alpha
	ASSS	Schwartz et al., 1987, A superactive insulin: [B10-Aspartic acid] insulin (human). Proc. Natl. Acad. Sci. USA 84:6408-6411
	ATTT	Takahashi, M., et al., GenBank Accession No. X67812
	AUUU	Takahashi, M., et al., GenBank Accession No. X15262
	AVVV	Tomac et al., 1995, Nature 373:335-339, Protection and Repair of the Nigrostriatal Dopaminergenic System by GDNF in vivo
	AWWW	Treanor et al., 1996, Nature 382:80-83, Characterization of a Multicomponent Receptor for GDNF.
	AXXX	Trupp et al., 1995, Journal of Cell Biology 130:137-148, Peripheral Expression and Biological Activities of GDNF, a New Neurotrophic Factor for Avian and Mammalian Peripheral Neurons
	AYYY	Trupp et al, 1996, Nature 381:785-789, Functional Receptor for GDNF Encoded by the c-ret Proto- oncogene
	AZZZ	Trupp et all., 1997, Journal of Neuroscience 17:3554-3567, Complementary and Overlapping Expression of Glial Cell Line-Derived Neurotrophic Factor (GDNF), c-ret Proto-oncogene, and GDNF Receptor-alpha Indicates Multiple Mechanisms of Trophic Actions in the Adult Rat CNS
	AAAAA	Tsuzuki et al., 1995, Spatial and temporal expression of the ret proto-oncogene product in embryonic, infant and adult rat tissues," Oncogene 10:191-198
	ABBBB	Van Heyningen, Veronica, 1994, Nature 367:319-320, One GeneFour Syndromes
	ACCCC	Van Weering et al., 1997, Journal of Biological Chemistry 272:249-254, Glial Cell Line-derived Neurotrophic Factor Induces Ret-mediated Lamellipodia Formation
	ADDDD	Vega, Q.C., 1996, Glial cell line-derived neurotrophic factor activates the receptor tyrosine kinase RET and promotes kidney morphogenesis, Proc. Natl. Acad. 93:10657-10661
	AEEEE	Worby et al., 1996, Journal of Biological Chemistry 271:23619-23622, Glial Cell Line-derived Neurotrophic Factor Signals through the RET Receptor and Activates Mitogen-activated Protein Kinase
	AFFFF	Yan et al., 1995, Nature 373:341-344, In vivo Neurotrophic Effects of GDNF on Neonatal and Adult Facial Motor Neurons
	AGGGG	Critical Synergy: The Biotechnology Industry and Intellectual Property Protection, Biotechnology

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Other Documents (include Author, Title, Date, and Place of Publication)				
Examiner	Desig.			
Initial	ID	Document		
	АНННН	GenCore databases. Amino acid sequence alignment between Applicants' SEQ ID NO: 13 and Sequence 3 of U.S. Patent number 6,025,157, issued February 15, 2000		
	AIIII	GenCore databases. Amino acid and nucleic sequence search comparisons between Applicants' SEQ ID NO:1, 2, 10 and 11 and U.S. Patent number 6,455,277, issued September 24, 2002		
	AJJJJ	Nucleic acid and amino acid database, Accession #AA049894 (1996)		
	AKKKK	Nucleic acid database, Accession #AA518362 (1996)		
	ALLLL	Nucleic acid database, Accession #O15316 (1997)		
	AMMMM	Nucleic acid database, Accession #AA049894 (1996)		
	ANNNN	Nucleic acid database, Accession #Q62997 (1995)		
	A0000	Nucleic acid database, Accession #035977 (1997)		
	APPPP	Nucleic acid database, Accession #W73681 (1995)		
	AQQQQ	Nucleic acid database, Accession #Q62997 (1997)		
	ARRRR	Nucleic acid database, Accession #P56159 (1997)		

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